

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 13, "Sterile Compounding Practices," Iowa Administrative Code.

The amendments were approved at the June 2, 2009, regular meeting of the Board of Pharmacy.

The proposed amendments clarify that the beyond-use date for a sterile compounded product shall be calculated to include any period of time during which the product is contained in a reservoir administration device and clarify the approved storage periods for high-risk compounded preparations depending on the temperature of the preparation during storage.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on July 21, 2009. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

These amendments are intended to implement Iowa Code sections 126.10, 155A.2, 155A.13, and 155A.28.

The following amendments are proposed.

ITEM 1. Amend rule **657—13.2(124,126,155A)**, definition of "Beyond-use date," as follows:

"Beyond-use date" means the date or time following compounding after which the preparation shall not be stored or transported. The beyond-use date is determined from the date or time compounding of the preparation is completed. Computation of the beyond-use date shall include the amount of time a compounded product is contained in a reservoir administration device.

ITEM 2. Amend paragraph **13.13(1)"e"** as follows:

e. For a sterilized high-risk preparation, in the absence of the preparation's passing a sterility test, the storage ~~periods~~ period beyond-use date shall not exceed the following:

- (1) At controlled room temperature, ~~for~~ 2 24 hours;
- (2) At a cold temperature, ~~for~~ 2 3 days; or
- (3) In a solid-frozen state between minus 25 and minus 10 degrees Celsius, ~~for~~ 2 45 days.